

November 19, 2016

Ruth Hughes Centers for Medicare and Medicaid Services Center for Medicaid and CHIP Services 7500 Security Boulevard Baltimore, MD 21244

Re: State of Illinois Behavioral Health Transformation 1115 Waiver Proposal

Dear Ms. Hughes:

Thank you for the opportunity to provide comments on the State of Illinois' proposed 1115 waiver, *Illinois Behavioral Health Transformation*.

Center for Lawful Access and Abuse Deterrence (CLAAD) is a not-for-profit organization that works to reduce prescription drug diversion, misuse, and abuse while advancing consumer access to high-quality care. It addresses this public health need by gathering and synthesizing information, disseminating its analysis, building coalitions, developing cross-industry consensus, and recommending sound public policies.

Since 2009, CLAAD's *National Prescription Drug Abuse Prevention Strategy* has encouraged the use of evidence-based treatment for individuals with opioid use disorder (OUD), including in the criminal justice system. The *National Strategy*, now in its fourth iteration, has been vetted and endorsed by 30 not-for-profit public health and safety organizations.

Illinois' waiver proposes a pilot program to provide treatment to individuals with OUD at the Illinois Department of Corrections (IDOC) and Cook County Jail (CCJ) who are preparing to return to their communities. We recommend that the proposed pilot program not be approved until it is revised to overcome the deficiencies described in this comment letter.

I. The pilot program should be expanded to include medication-assisted treatment upon entry into a correctional facility.

In 2015, 1,779 individuals entered the IDOC with substance use disorders that involved opioids or heroin. For individuals with OUD, the earlier that treatment is offered in the disease process, the greater the likelihood of positive outcomes. Yet, the pilot program does not provide for treatment to individuals with OUD upon entry. Rather, as proposed, treatment would start one month prior to release. By waiting until the end of qualifying inmates' sentences to initiate treatment, Illinois is missing out on an important opportunity to increase the likelihood of positive treatment outcomes and effectuate a significant change to inmates' lives, as well as the community at large. To maximize effectiveness, a pilot program for treating individuals with

¹Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition), NATIONAL INSTITUTE ON DRUG ABUSE (accessed Nov. 17, 2016), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/principles-effective-treatment.

OUD needs to be designed so that treatment is immediately available to individuals when they first enter a correctional facility and continues through the incarceration period, even if the individual has yet to be sentenced.

Under current law, treatment may be covered by Medicaid, or possibly private insurance, prior to conviction and sentencing. For example, under the Patient Protection and Affordable Care Act and its implementing regulations, incarcerated individuals are not eligible to buy an insurance plan on the marketplace; however, an individual "is not considered incarcerated if [he or she] is in jail or prison pending disposition of charges." In other words, a person is not incarcerated if being held but not yet convicted of a crime. Therefore, the pilot program could be designed to start treatment for individuals with OUDs as early as the initial pre-conviction holding period before Medicaid coverage is terminated.

Furthermore, once an inmate enters a correctional facility, deliberately failing to provide the individual adequate treatment for a known medical condition may violate his or her constitutional rights.³ For example, some courts have held that an incarcerated individual can establish a claim that his or her constitutional rights were violated when the correctional facility knew the individual had OUD and was receiving medication-assisted treatment (MAT)or dependent on heroin at the time of incarceration, and nevertheless forced the individual to detoxify and suffer withdrawal symptoms without adequate medical supervision, including not providing access to medication.⁴

There are models for treatment programs for incarcerated individuals with OUD that provide comprehensive treatment throughout the incarceration period with documented results. For example, Rikers Island, New York's main jail complex, offers treatment with all medications approved by the U.S. Food and Drug Administration (FDA) for the treatment of OUD and offers treatment throughout incarceration, including (1) initiating treatment for inmates who enter the facility with OUD, (2) maintaining treatment for individuals who enter the facility already on treatment, and (3) encouraging inmates with OUD to begin treatment before they leave the jail.⁵ Research has demonstrated that treatment initiated during incarceration and continued upon release leads to positive outcomes, including reduction in illicit opioid use; risky behavior, such as needle sharing, that can lead to the contracting and transmitting serious infectious diseases (such as HIV and hepatitis C); and criminal recidivism.⁶

Therefore, given the possible constitutional implications of not providing adequate care for

² *Incarcerated People*, HEALTHCARE.GOV (accessed Nov. 13, 2016), https://www.healthcare.gov/incarcerated-people/; *Incarceration and the Marketplace*, CENTERS FOR MEDICARE AND MEDICAID SERVICES (accessed Sept. 13, 2016), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Incarceration-and-the-Marketplace-FAQs-05-03-2016.pdf.

³ See Estelle v. Gamble, 429 U.S. 97, 103 (1976); Farmer v. Brennan, 511 U.S. 825, 828 (1994).

⁴ See Foelker v. Outagamie County, 394 F.3d 510 (7th Cir. 2005); U.S. ex rel. Walker v. Fayette Cnty., 599 F.2d 573, 574 (3d Cir. 1979) (per curiam).

⁵ At Rikers Island, a Legacy of Medication-Assisted Opioid Treatment, THE PEW CHARITABLE TRUSTS, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/05/23/at-rikers-island-a-legacy-of-medication-assisted-opioid-treatment, (May 23, 2016).

⁶ Anna Pecoraro and George E. Woody, *Medication-assisted treatment for opioid dependence: making a difference in prisons*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042317/ (Jan, 14, 2011).

inmates with OUD, and the demonstrated benefits of early intervention and treatment, we urge Illinois to modify its pilot program to address individuals' treatment needs as early as the initial pre-conviction holding period, and not limit the program to a period 30 days prior to release.

II. The pilot program is not consistent with federal and state policy on treatment of OUD.

The pilot program does not provide access to all FDA-approved MAT options, which is inconsistent with federal and state policy. ⁷ MAT is a comprehensive treatment approach that combines counseling, behavioral therapy, and FDA-approved medications to treat OUD. Medications approved to treat OUD include methadone, buprenorphine, and naltrexone. Evidence shows that MAT is effective in treating OUD and reducing drug-related disease and criminal recidivism. ⁸ But for MAT to be effective, physicians need the full array of available treatment options to tailor treatment to the unique needs of each patient. Treatment for OUD is optimized when it is individualized. ⁹ An individualized treatment program includes having access to *all* FDA-approved medications for the treatment of OUD—a fact that is acknowledged by the federal government and by the state of Illinois. ¹⁰ Yet by limiting treatment for incarcerated individuals with OUD to injectable naltrexone, the proposed program presents a one-size-fits-all approach, which sets the program up for ineffective and lackluster results.

We encourage Illinois to adopt a model that incorporates all available FDA-approved medications for treatment of OUD. A pilot program could be designed so that methadone is administered through a co-located opioid treatment program (OTP); naltrexone by a healthcare

 $^{^7 \} See, \ National \ Drug \ Control \ Strategy, \ White \ House \ Office \ of \ National \ Drug \ Control \ Policy, \\ https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/$

²⁰¹⁵_national_drug_control_strategy_0.pdf; *Medication Assisted Treatment for Opioid Use Disorders*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, https://www.federalregister.gov/documents/2016/03/30/2016-07128/medication-assisted-treatment-for-opioid-use-disorders; *Buprenorphine*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (last updated May 31, 2016); *Drugs, brains, and behavior: The science of addiction*, NATIONAL INSTITUTE ON DRUG ABUSE (NIH Pub No. 14-5605) https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/soa_2014.pdf (2014); *Facing Addiction in America*, SURGEON GENERAL, https://addiction.surgeongeneral.gov/ (2016); Illinois Public Act 099-0480.

⁸ Statement by Nora D. Volkow, M.D. on Treating Addiction as a Disease: The Promise of Medication-Assisted Recovery, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2010/06/treating-addiction-disease-promise-medication-assisted-recove, June 23, 2010.

⁹ Richard Gustin et.al, *Individualizing Opioid Use Disorder (OUD) Treatment: Time to Fully Embrace a Chronic Disease Model*, JOURNAL OF REWARD DEFICIENCY SYNDROME, http://blumsrewarddeficiencysyndrome.com/articles/v1n1/jrds-003-richard-gustin.html; *Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition)*, NATIONAL INSTITUTE ON DRUG ABUSE https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/principles-effective-treatment.

¹⁰ See National Drug Control Strategy, WHITE HOUSE, https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/2015_national_drug_control_strategy_0.pdf (2015); White House Takes Important First Step Toward Fixing Broken Drug Court System, DRUGPOLICY.ORG. http://www.drugpolicy.org/blog/white-house-takes-important-first-step-toward-fixing-broken-drug-court-system Febuary 6, 2015.; SAMHSA bans drug court grantees from ordering participants off MAT, ALCOHOLISM & DRUG ABUSE WEEKLY, http://www.alcoholismdrugabuseweekly.com/m-article-detail/samhsa-bans-drug-court-grantees-from-ordering-participants-off-mat.aspx Feb 16, 2015; Illinois Public Act 099-0480.

provider onsite, as proposed in the waiver; and buprenorphine by a co-located OTP or visiting outpatient healthcare provider.

Additionally, treatment with buprenorphine implants could be administered by a health care practitioner after the individual is stabilized on oral buprenorphine. Access to treatment with the buprenorphine implants would further reduce the possibility of diversion. The waiver correctly implies that products that are directly administered to the patient by a healthcare provider, and therefore, not dispensed to the patient for self-administration, reduce the possibility of diversion. The White House Office of National Drug Control Policy, National Institute on Drug Abuse, FDA and have all recognized that novel delivery systems, such as injectables and implantables, can reduce the risk of medication diversion. We encourage Illinois to include all FDA-approved medication, including injectables and implantables into its revised program.

Illinois has a unique opportunity to create a pilot program that has the potential to transform its criminal justice system by improving treatment outcomes, decreasing costs, reducing recidivism, and helping individuals towards recovery. However, a successful program needs to incorporate all FDA-approved medications for OUD and treat individuals throughout the entire term of their incarceration. As such, we urge the Centers for Medicare and Medicaid Services to not approve Illinois' proposed waiver and recommend that Illinois revise its pilot program to include all available FDA-approved medications and treatment throughout the entire term of the incarceration.

Thank you for considering our recommendations on this matter.

Sincerely,

Shruti R. Kulkarni Policy Director

Shrut Luckan

¹¹Psychopharmacologic Drugs Advisory Committee, U.S. FOOD AND DRUG ADMINISTRATION. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDr ugsAdvisoryCommittee/UCM500364.pdf (Jan 12, 2016); *Fiscal Year 2017 Budget Information - Congressional Justification for National Institute on Drug Abuse*, NATIONAL INSTITUTE ON DRUG ABUSE (accessed Nov, 17, 2016) https://www.drugabuse.gov/about-nida/legislative-activities/budget-information/fiscal-year-2017-budget-information-congressional-justification-national-institute-drug-abuse; *National Drug Control Strategy*, WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY, https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_2013.pdf (2013).